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PRINCIPAL INVESTIGATOR: Heidi R Flori MD, FAAP

CONTRACTING ORGANIZATION: Children's Hospital and Research Center Oakland

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Gantt Chart for 2012 Annual Report

Task	2011 Q4	2012 Q1	2012 Q2	2012 Q3	2012 Q4	2013 Q1	2013 Q2	2013 Q3	Status
1									On Schedule
1a									Yet to Start
1b									Yet to Start
1c									Yet to Start
2									On Schedule
2a									Yet to Start
2b									Yet to Start

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Introduction

Many medical emergencies, such as overwhelming infection, traumatic brain injury and stroke, result in better patient outcomes (including improved chance of survival) with *time-sensitive initial* patient management. These conditions can occur whether you are an adult or a child. Unfortunately, the American Academy of Pediatrics and American College of Emergency Physicians estimate that only 6% of hospitals have “essential” pediatric supplies for pediatric emergencies. Importantly, many pediatric specific interventions, such as fluid and blood product resuscitation, antibiotic and osmotherapy administration and seizure prophylaxis, are often NOT technically sophisticated and can easily be implemented by non-specialized medical personnel if transport personnel have easy access to clinical decision support (CDS) technology with appropriate time-management prompts. Improperly managed, however, the clinical outcome for the patient can include secondary injuries and even death.

Transport clinicians, particularly those responding to trauma or disaster calls, must be competent to initiate care in both adults and children with a wide array of prior medical problems. Although educational materials may be at hand to the transport clinician while they are “en route” to the sending facility, these references are very rudimentary and less useful once care of the patient has been assumed. The transport environment can be physically harsh for the patient, transport personnel and equipment. Once transport to the receiving facility is underway, communication to the receiving hospital is often impractical and/or technically infeasible. Care during transport must continue, however, given that transport is inherently also subject to unforeseen delays due to weather, traffic or other mechanical problems.

Discomfort on the part of an unspecialized transport team and/or lack of appropriate equipment to manage patients of smaller size, particularly children, can and has proven to be a substantial challenge during evacuation from mass casualty incidents, such as occurred after Hurricane Katrina. This is not surprising given that, per a 2003 Institute of Medicine report, “initial efforts at disaster planning did not incorporate the needs of children.” The situation in the military venue is further challenged in that pediatric subspecialists, such as pediatric intensive care and neurosurgical specialists, are not available in the Role 1 or 2 environments, yet critically ill and injured children, frequently with penetrating injuries and acute neurosurgical needs, are often seen in those venues. Recent data reported by Spinella et al. and Burnett et al each indicate that in-hospital mortality for pediatric patients admitted to US Army military hospitals in Iraq and Afghanistan is higher than that for adult coalition and non-coalition patients.

The overarching goal of this application is *to develop and test* the efficacy of a comprehensive, interfacility transport system that maximizes clinical decision support (CDS) opportunities available to the transport team. This system will embody the visual interface available through telemedical infrastructure combined with a real-time, hand held, electronic medical record (EMR) compatible and interactive clinical decision support (CDS) tool.

Body

Hypothesis:

Our primary hypothesis is that the application of an interfacility telemedical infrastructure that combines an EMR-compatible, clinical decision support application on a handheld device, combined with a visual interface, will lead to greater satisfaction, better compliance with best

practice recommendations, more accurate diagnoses, decreased adverse events, and better patient outcomes.

Technical Objectives:

Objective/Task 1: To create and test a portable, robust, interactive and hand-held application to allow time-sensitive CDS algorithms to be used in the transport of critically ill children and adolescents from remote hospital locations to our tertiary care facility.

Subtask 1a: Will the use of the pediatric septic shock CDS algorithm developed and implemented in our prior CHIPERS grant on both ground and air interfacility transport improve compliance with Surviving Sepsis campaign algorithms and decrease end organ dysfunction in children and adolescents with severe sepsis and septic shock?

Subtask 1b: Will the use of the CHRCO pediatric trauma guidelines on both ground and air interfacility transport enable more timely and appropriate medical management of children and adolescents with severe traumatic brain and other multi-organ system injuries?

Subtask 1c: Will the use of the CHRCO pediatric diabetic ketoacidosis (DKA) CDS algorithm on both ground and air interfacility transport improve compliance with time-sensitive management goals of children and adolescents with DKA, a life-threatening manifestation of diabetes that comprises over 10% of all pediatric transports to CHRCO PICU?

Objective/Task 2: To create and test the added utility of a portable yet high-fidelity visual interface in the management and triage of critically ill children and adolescents at the start of ground and air interfacility transports.

Subtask 2a: Will the use of a high-fidelity visual interface on ground and air interfacility transport of critically ill children and adolescents improve the delivery of care by medical transport personnel, as measured by decreased adverse events on transport and improved transport personnel confidence?

Subtask 2b: Will the use of a high-fidelity visual interface on ground and air interfacility transport improve the accuracy of diagnosis and appropriateness of triage for critically ill children and adolescents?

Study Design:

This is a prospective comparison of the management, efficiency and triage of critically ill children and adolescents before and after the implementation of a new ground and air transport electronic clinical decision support system with an interactive visual interface.

Problems Encountered:

Although we have made great progress within the last year, we have been unable to complete the project as initially desired and have requested a one year, no cost extension.

Three principal reasons for the delays have been identified and addressed as follows:

1) Children's Hospital and Research Center Oakland (CHRCO) signed contracts with and is actively moving toward the transition to the EPIC electronic medical record system. Anticipated

“go-live” date for our hospital with the EPIC system is autumn of 2013. Accordingly, there has been a shift in personnel to adequately staff this transition. This shift in personnel has affected some of the members of our current transport grant investigation. Specifically, Ms. Jenny Tan, the CHRCO PICU nurse educator and transport coordinator, has moved to the EPIC transition team. Her role on our transport grant as coordinator and liaison between the hospital based research team and the Reach research team will now be served by Ms. Erin Silva, a senior PICU nurse at CHRCO. She has been thoroughly oriented to her new role on this grant and she has completed CITI Human Subjects Certification. Ms. Julie Simon, our CHRCO PICU Research Nurse Coordinator, has also transitioned to the EPIC team. Her position is not filled but interviews are underway. Her duties are currently being shared by the remaining working group. The role of Information Technology Specialist had been filled by Mr. Jim Ort, a long time senior IT specialist at CHRCO. He, too, has transitioned to the EPIC move. His role has been successfully taken over by Mr. Ryan McNulty who also has several years experience as senior IT personnel at CHRCO.

2) Although all the information technology concept and hardware work has been easily undertaken here at CHRCO, we have had to outsource some of our computer software needs to a commercial vendor, Digital Ink. Importantly, Digital Ink has served as the creator of the currently used electronic documentation system in use by Reach Air Medical transport personnel and has plans to innovate their Windows-based software toward other platforms including the Android platform, which is currently one of the hand-held device platforms that we are investigating for use in this research. We feel strongly that Digital Ink’s experience in serving documentation needs for use on medical transport of the critically ill patient will serve as a key strategy to improved end user compliance with the move to a hand-held CDS device. Sub-contracting agreements have been completed.

3) Despite submission of our application to the USAMRMC OPR in Fall 2012, we were not able to receive final electronic notification from Ms. Laura Brosch that the USAMRMC ORP, HRPO had found our protocol to comply with applicable DoD, US Army and USAMRMC human subjects protection requirements until June 19, 2012. Fortunately, we were informed that this was deemed a “no greater than minimal risk study” and was “approved for accrual of approximately 500 datasets with waiver of informed consent.” The length of time required to receive approval from the USAMRMC ORP was unanticipated on our part and has delayed our ability to assess the outcomes of our transported patients *before* initiation of the handheld clinical decision support tools and visual interface.

Accomplishments according to proposed tasks:

Our “team” includes all CHRCO based physician and nurse investigators as well as members from CHRCO Information Technology, Mr. Jeff Dunbar, CEO of Offsite Care Telemedical Consultation Co., Dr. Gary McCalla, Reach Air Mediplane Medical Director, and CAPT Jon Woods, MD (military consultant) to discuss the plans and progress of the handheld equipment development.

We initiated our team discussions with a “kick off” conference held at Reach Air Medical offices in Santa Rosa, California on Sept 19, 2011. Since that event, our team members have met weekly to insure good understanding and progress across the clinical teams, information technology teams and our consultants. Our project received CHRCO Institutional Review Board approval on October 5, 2011 as a minimal risk study with waiver of consent. We hosted Mr. Robert Connors, our GOR for the first year of study, on February 27, 2012 for a successful site visit. Finally, Dr. Flori

presented an update of the progress and future plans for this project at a TATRC PLR meeting in Frederick, Maryland on August 7, 2012.

Objective/Task 1: To create and test a portable, robust, interactive and hand-held application to allow time-sensitive CDS algorithms to be used in the transport of critically ill children and adolescents from remote hospital locations to our tertiary care facility.

We continue to make great progress in our **Phase 1 research and development** of our clinical decision support (CDS) device. Our working group has many facets – the clinical team has been working steadily on the development and refinement of our concept protocol treatment algorithms and assessing how these algorithms will be best received and utilized by our transport personnel. Our information technology team has been continually assessing handheld devices and visual interface systems and working with our computer programmers to “translate” our transport documents and our CDS algorithms into “code.” As a result of our year-long efforts, our prototype device is nearing completion as of this writing with our planned **Phase 2 “Transition/Run-in”** phase tentatively set for November 2012 and our **Phase 3 “Go-Live”** planned for December 2012.

The majority of the first year involved assessment of existing technology options in comparison to transport “needs” and “constraints” with particular regard for size, weight and durability of equipment (i.e., temperature, water and physical impact resistance). We learned that both the military’s and Reach MediPlane’s chosen platform for documentation is Windows based and we have transitioned our computer software programming and device selection to start with Windows based technology, although ultimately we look forward to our clinical decision support technology being platform “agnostic.”

The treatment algorithms for our three concept protocols in Subtasks 1a, b and c (severe sepsis, traumatic brain injury and diabetic ketoacidosis) have been edited and verified both by the clinician intensivist investigators (Flori and Cvijanovich) and by end user investigators at Reach MediPlane (Dr. Gary McCalla and others). Drs. Flori and Cvijanovich have created “goto” meeting lectures describing the DoD project and each of the three treatment algorithms. These lectures have been used to assist in educating the end user transport clinician team as this project moves forward.

Collaboration and appreciation of prior allied work is vital for success of subsequent research. Along these lines, we have engaged in several teleconferences with the Starix Technology Think-a-Move personnel on the success and applicability of their speech recognition system as it may ultimately integrate with the platform we are currently developing. In addition, Dr. Flori had lengthy discussions with Comm. Emory Frye from San Diego Naval Hospital before his transition to the civilian sector to discuss and learn from his decision support research in the integrated medical “suitcase” and closed loop mechanical ventilator feedback systems.

The execution of our time-sensitive treatment algorithms often requires point of care blood gas and analyte testing currently NOT within scope of practice for most remote emergency room personnel and for many transport clinicians. Accordingly, we have completed necessary multi-disciplinary discussions and developed methodology to allow the Reach transport clinicians to run their own point of care laboratory testing using the EPOC point of care device (Alere, Inc.). Plans are underway to gain Reach transport personnel certification in running these point of care laboratory results, thus increasing potential for compliance with our time-sensitive management

algorithms. Addition of this technology for use on transport has the potential to improve the standard of patient care on transport, in and of itself.

The handheld device is also going to be used for documentation purposes by transport personnel. Transport documents from CHRCO and Reach have been reviewed. Most documentation of transport proceedings occur after transport is completed and the transport clinician is back at their “home base.” Hand off communication to the receiving tertiary medical center team is primarily verbal. Completion of the written transport record after the transport can result in delayed communication of important transport elements that may have been omitted during the verbal handoff, as well as inaccuracies in data transfer. Therefore, the investigator team has created an “interim evaluation” document that includes vital elements for handoff communication to the receiving institution clinical team. This “interim document” will be completed in real time, transmitted to the receiving tertiary medical center team in real time and can also auto-populate the more lengthy case report form that the transport clinician will complete when once again at the “home base.” Again, addition of this written hand off communication methodology in and of itself has the potential to improve the standard of patient care on transport.

In order to ensure that the use of the handheld device and CDS algorithms do not negatively interfere with transport personnel workflow, we have developed a survey intended for transport personnel. The survey, developed by Dr. Flori and Ms. Silva, has been reviewed by Dr. McCalla and other Reach transport personnel. This survey will be administered both before and after implementation of the CDS tools.

Objective/Task 2: To create and test the added utility of a portable yet high-fidelity visual interface in the management and triage of critically ill children and adolescents at the start of ground and air interfacility transports.

We regularly engage our telemedical consultants at Offsite Care, Inc. to insure that optimal visual interface requirements are being assessed and that federal regulatory requirements are being met. We have also engaged Vidyo, Inc. encryption services to enable secure transmission of visual images from sending facility to our receiving command center.

We have investigated hand-held camera devices with particular regard for temperature, water and physical impact resistance. Transport personnel are likely to “wear” the device on their helmets, on their collar, on their shirt or on their head (like a headband). The Contour visual interface device is currently our suggested prototype device as this device is small, high-fidelity and can be worn on a helmet, on one’s hand, attached to clothing, etc. Another device, the Looxcie, is under consideration as well and will be tested with the transport personnel.

Future Work:

- 1) Our major focus this coming year will be to deploy the handheld clinical decision support (CDS) device and visual interface system. The remaining steps include:
 - a. We will be testing the Dell Latitude tablet with the 3 CDS concept protocols and interim patient care report features installed.
 - b. We will complete the CHRCO transport command center receiving station including wireless “hotspot” with encryption technology to receive images in a secure fashion.

- c. November 2012 is anticipated to be our Phase 2 “Transition/Run In month.” During this time, we will go to the Reach Air Medical sites in Santa Rosa, Concord, and Stockton, California to give detailed review of the handheld device, the concept protocols, the interim patient care report and the EPOC point of care testing device with all potential transport personnel. All personnel participating in this project will complete a competency “sign off.” This is scheduled to occur at multiple Reach “base meetings” during the month of November.
- d. Phase 3 “Go live” deployment of handheld device for use on pediatric transports to the CHRCO PICU is tentatively set for December 2012.
- e. We will administer an anonymous survey of transport clinicians both before and after use of the handheld device and the visual interface.
- f. We will complete our Phase 2 “run-in” testing, competency training and Phase 3 “go live” deployment of the visual interface with transport clinicians after successful implementation of the handheld device. This is tentatively February 2013.
- g. Throughout Phase 3, both before and after implementation of the handheld device and visual interface system, we will analyze the following: 1) assessment of algorithm compliance, 2) adverse events on transport and 3) survey results.
- h. We will continue to develop clinical decision support algorithms in other needed areas of pediatric critical care transport including, but not limited to:
 - i. status epilepticus,
 - ii. status asthmaticus,
 - iii. sedation and analgesia,
 - iv. mechanical ventilator management for children with and without acute lung injury.
- i. Finally, this next year will include manuscript preparation and submission of results for presentation at national meetings.
- j. We are already beginning preparations for “next phases” of product development. See #2 below.

2) The current grant application seeks to create a “passive” CDS system wherein the transport clinician can “scroll” the medical application in real time before and during the transport. Ultimately, however the goal is to create an “active” CDS system. Therefore, the algorithms currently under evaluation are also being assessed for areas in which “smart” interaction between the transport clinician and the device can be created. One example previously described is wherein the transport personnel can “link” to other decision algorithms (i.e., transport personnel use sepsis algorithm and find the patient to be in respiratory distress. Algorithm can “link” to respiratory distress algorithm.) Another example involves streaming patient data into the CDS algorithm such that the algorithm can prompt the clinician when certain patient vital sign parameters or laboratory results are out of a desired range.

The current grant application does not include this level of “interactivity” in its scope and would require additional grant funding sources, development time and expanded computer software expertise to complete. Accordingly, we have been seeking our “next opportunities” to carry our project forward at the end of our current anticipated “end” date of October 2013.

Accordingly, Dr. Bert Lubin, CHRCO CEO, Dr. Flori and Dr. Cvijanovich have engaged in a teleconference with TATRC representative, Dr. Charles Petersen. Dr. Petersen encouraged us to pursue technology transfer alliances in industry outside of the federal government. We have since

engaged Mr. Ori Sasson, member of the CHRCO Board of Directors and seasoned executive and entrepreneur, to assist us in identifying appropriate resources to continue our project beyond the scope of this grant. Mr. Sasson has been added to our investigator pool as a “mentor” with in-kind support for his time in this endeavor. Plans for protection of intellectual property during this and future ventures are underway with Children’s Hospital Oakland Research Institute legal counsel, Ms. Suzanne Haendle, JD.

Key Research Accomplishments

- 1) Approvals from both CHRCO IRB and USAMRMC OPR as minimal risk study with waiver of consent.
- 2) Nearing completion of Phase 1, “research and development” of our handheld clinical decision support platform in preparation for Phase 2 “Transition/run-in” and Phase 3 “Go-Live” deployment in 2012 Q4.
- 3) Completion of clinical decision support tools in our 3 concept protocol areas of severe sepsis/septic shock (Appendix 1), traumatic brain injury (Appendix 2) and diabetic ketoacidosis (Appendix 3).
- 4) Completion of transport personnel survey tool to assess satisfaction with device, visual interface, and algorithms.
- 5) Completion of negotiations and requirements to improve current scope of practice on all pediatric critical care transports including:
 - a. Use of point of care analyte and blood gas testing
 - b. Real-time patient care data collection and written (in addition to current standard of care – verbal) hand off communication.
- 6) Preparation for “next phases” of platform development after the current scope of work elucidated in this TATRC project is complete. Specifically, we plan to convert these “passive” clinical decision support tools to “active, integrated and platform agnostic” clinical decision support tools with streaming of vital sign and point of care analyte testing into each algorithm, while also maintaining FDA standards for mobile medical health technology.

Reportable Outcomes

- 1) Plans and progress have been presented at the August 7, 2012 TATRC PLR meeting in Frederick, Maryland.
- 2) This project has been presented as a CHRCO Grand Rounds lecture on clinical decision support tools for management of time-sensitive, critical pediatric illness on 1/31/2012.

Timeline Modification

As described in the “Problems” section above, we have submitted a request for a one year, no cost extension in order to complete Phases 2 and 3 of the project as well as complete data analysis and manuscript preparation.

Conclusions:

Recent evidence suggests that the original benefit of the “scoop and run” or “golden hour” concept of transport no longer applies, particularly for those patients with medical emergencies such as septic shock, traumatic brain injury or stroke. Although expeditious management at the sending facility is still warranted, there is mounting evidence that aggressive treatment of adults and children in the field and en route, often with technically unsophisticated strategies like temperature control, fluid resuscitation and blood pressure management, can improve clinical outcomes.

Specialized transport teams may also improve outcomes particularly for neonatal and pediatric patients but they are costly and not always available, such as during trauma or disaster scenarios. Targeted and timely clinical decision support, whether by electronic and/or visual interface with clinicians at the receiving institution transport command center, may help transport personnel hone medical management further, resulting in improved patient morbidity and mortality. On the other hand, the thoughtless and inelegant application of technology that needlessly lengthens transport times and/or results in poor communication has the potential to interrupt the otherwise organized flow of transport with negative impact on the patient.

The overarching goal of this application has been to develop and test the efficacy of a comprehensive, interfacility transport system that maximizes clinical decision support (CDS) opportunities available to the transport team. This system will embody both the visual and auditory interface available through telemedical infrastructure combined with a real-time, hand held, electronic medical record (EMR)- compatible and interactive clinical decision support (CDS) tool. To complete this goal, we have successfully engaged our existing ground and air critical care transport (Reach Air Medical, Inc) infrastructure, our OffSite Care critical care telemedicine platform and Children’s Hospital and Research Center Oakland (CHRCO) Information Technology specialists, and key consultants in the military, CAPT. Jon Woods, MD, and Comm Emory Frye MD, and have contracted services from Digital Ink Inc, computerized medical software technologists.

By combining this array of resources, we are poised to implement improved strategies of communication with pre-hospital and transport personnel, with the ultimate goal of providing more exact and timely interventions, minimizing transport time to our receiving facility and therefore improving the morbidity and mortality of our transported critically ill pediatric patients. As we proceed with the implementation of our proposed handheld and visual tools, we have a plan to closely examine adherence to our management guidelines, adverse events on transport and feedback from the transport clinicians themselves on the usability and next phases of design. As the CDS currently developed and about to be deployed is still essentially passive in nature, we must continue to develop improvements beyond the scope of this grant. To this end, we are actively seeking guidance from software leaders and entrepreneurial mentors to further develop our technology into more robust, platform agnostic and interactive clinical decision support methodology.

Relevant References:

Lowe, C., Pediatric and neonatal interfacility transport medicine after mass casualty incidents. J Trauma, 2009. 67(2 Suppl): p. S168-71.

IOM, Emergency Care for Children: Growing Pains, in Future of Emergency Care, G. Warden, Editor 2007, Institute of Medicine.

Martin, J., R. Teff, and P. Spinella, Care of pediatric neurosurgical patients in Iraq in 2007: clinical and ethical experience of a field hospital. *J Neurosurg Pediatr*, 2010. 6(3): p. 250-6.

McGuigan, R., et al., Pediatric trauma: experience of a combat support hospital in Iraq. *J Pediatr Surg*, 2007. 42(1): p. 207-10.

Spinella, P., M. Borgman, and K. Azarow, Pediatric Trauma in an austere combat environment. *Crit Care Med*, 2008. 36(7 Suppl): p. s293-6.

Burnett, M., et al., Pediatric Care as Part of the US Army Medical Mission in the Global War on Terrorism in Afghanistan and Iraq, December 2001 to December 2004. *Pediatrics*, 2008. 121: p. 261-265.

Stroud, M., et al., Enhanced Monitoring Improves Pediatric Transport Outcomes: A Randomized Controlled Trial. *Pediatrics*, 2011. 127: p. 42-48.

Dellinger, R., et al., Surviving Sepsis Campaign: international guidelines for management of severe sepsis and septic shock: 2008. *Crit Care Med*, 2008. 36(1): p. 296-327.

Adelson, P., et al., Guidelines for the Acute Medical Management of Severe Traumatic Brain Injury in Infants, Children and Adolescents. *Ped Crit Care Med*, 2003. 4(3): p. Suppl.

Brott, T., et al., 2011 Guideline on the Management of Patients with Extracranial Carotid and Vertebral Artery Disease: Executive Summary. *Stroke*, 2011(Jan 31, epub ahead of print).

Winsor, G., et al., Inadequate hemodynamic management in patients undergoing interfacility transfer for suspected aortic dissection. *Am J Emerg Med*, 2005. 23(1): p. 24-9.

Orr, R., et al., Pediatric Specialized Transport Teams are Associated with Improved Outcomes. *Pediatrics*, 2009. 124: p. 40-48.

Butterfield, L., Regionalization for respiratory care. *Pediatr Clin North Am*, 1973. 20: p. 499-505.

Pettett, G., et al., An analysis of air transport results in the sick newborn infant: part 1. The transport team. *Pediatrics*, 1975. 55: p. 774-82.

Pollack, M., et al., Improving the outcome and efficiency of intensive care: the impact of an intensivist. *Crit Care Med*, 1988. 16: p. 11-7.

Pollack, M., et al., Improved outcomes from tertiary center pediatric intensive care: a statewide comparison of tertiary and nontertiary care facilities. *Crit Care Med*, 1991. 19: p. 150-9.

Ajizian, S. and T. Nakagawa, Interfacility Transport of the Critically Ill Pediatric Patient. *Chest*, 2007. 132: p. 1361-7.

MacDonald, R., B. Banks, and M. Morrison, Epidemiology of adverse events in air medical transport. *Academic Emergency Medicine*, 2008. 15: p. 923-931.

Carcillo, J., A. Fields, and C.d. Forca-Tarefa, Clinical practice parameters for hemodynamic support of pediatric and neonatal patients in septic shock. *J Pediatr*, 2002. 78(6): p. 449-66.

Glaser, N., et al., Risk factors for cerebral edema in children with diabetic ketoacidosis. *N Engl J Med*, 2001. 344(4): p. 264-9.

Matos, R., et al., Increased mortality rates of young children with traumatic injuries at a US Army Combat Support Hospital in Baghdad, Iraq, 2004. *Pediatrics*, 2008. 122: p. e959-966.

AAP, The Youngest Victims: Disaster Preparedness to Meet the Needs of Children, 2002, American Academy of Pediatrics: Washington, DC.

Appendices:

- 1) Pediatric Severe Sepsis/Septic Shock Management Algorithm
- 2) Pediatric Traumatic Brain Injury Algorithm
- 3) Pediatric Diabetic Ketoacidosis Algorithm

Supporting Data: none

CHILDREN'S HOSPITAL & RESEARCH CENTER OAKLAND – SEVERE SEPSIS CPG

These guidelines are used at Children's Hospital & Research Center Oakland and are provided as a reference.*

Time Zero**

- 1) **Concern for shock**-Besides fever, tachycardia, and hypotension, some patients present initially only with altered mental status and decreased perfusion (delayed or flash capillary refill) – **REFER TO RAPID SEPSIS ASSESSMENT TOOL!**
- 2) Call **Medstat**.
- 3) Place **oxygen** on all patients!
- 4) Initiate attempts at **IV access** and **lab testing (OK to use Broviac/central line)**:
(POC tests-blood gas, glucose, lytes, lactate. Also CBC, chem 8, blood cultures)
- 5) Know where **IO** equipment is!

0-15 Minutes – START!

- 1) If no IV access by 5 minutes, **consider IO!**
- 2) **PUSH** fluids (isotonic crystalloid) *by hand* over 5 minutes if possible, not on a pump, 20 ml/kg IV, repeat until perfusion improves unless rales or hepatomegaly develop, maximum 60 ml/kg IV .
(Fluid resuscitation will take longer than 15 minutes, but initiate here!)
- 3) Assess **point of care** results and **treat hypoglycemia and hypocalcemia**
- 4) Order **antibiotics** and give ASAP (Goal for first dose to be in by 30 minutes!)
- 5) Order **inotropes** to bedside, use if BP low *and* 2nd IV available, MAY give inotropes through PIV or IO, even on the ward!
(Dopamine 5-10 mcg/kg/min or epinephrine 0.05-0.3 mcg/kg/min)

15-60 Minutes – REASSESS!

- 1) Consider **hydrocortisone** for adrenal insufficiency! (25 mg IV under 6 months, 50 mg IV up to 9 years, 100 mg IV if 10 years or older)
- 2) Reconsider need for **inotropes** if not already being given.
- 3) Reassess:
 - A) Appropriate **cultures** have been drawn,
 - B) **Antibiotics** given, and
 - C) Sufficient **fluid resuscitation** given

1-4 Hours (Even if not yet in PICU)

If blood pressure is *not* normalized, tachycardia is *not* resolved, or still needs inotropes;

- 1) Consider need for more **fluid boluses** (up to 200 ml/kg).
- 2) Consider adjusting **inotropes** upwards or adding vasopressors (norepinephrine or vasopressin).
- 3) May need **blood transfusion**.
(Surviving Sepsis Guidelines suggest goal Hgb 10)

- 4) Consider **pericardial effusion, pneumothorax, and increased intra-abdominal pressure.**
Treat if found.
- 5) May require **central line** for access and/or monitoring.
- 6) Consider repeat POC blood gas with lytes and glucose.

**** Time zero** is the first point at which anyone considers that a child might be septic. Other times are given as ranges with the idea that every point will have been initiated, or at least considered, by the end of the time frame.

* Based on Surviving Sepsis Campaign Guidelines: Intensive Care Med (2008) 34:17–60, No.3; www.survivingsepsis.org

Appendix 2:

Pediatric Traumatic Brain Injury Protocol

Time zero

1. Assess, treat, stabilize **Airway – Breathing – Circulation** (See Assessment and Standard Care for all Patients protocols).
2. Perform and record **neurologic exams** at least **every 5 minutes** (*timer q5' with reminder of SpO2 goal and BP goal as well*).
 - A. Level of consciousness
 - B. Glasgow Coma Scale (*link to GCS, both pediatric and adult*)
 - C. Pupil equality, size and reactivity.
3. Secure airway with ETT if: (*link to "Endotracheal intubation, oral"*)
 - A. Persistent SpO2 < 94% despite optimal non- invasive oxygen supplementation
 - B. Hypercarbia or Etco2 > 45 mmHg
 - C. GCS < 8 or motor GCS score < 2
 - D. Pupil dysfunction (asymmetric or non- reactive) or disconjugate gaze altered from baseline
 - E. Loss of gag reflex
 - F. Any clinical signs of herniation: Cushings= systemic hypertension + bradycardia and irregular respirations
 - G. Decorticate or decerebrate posturing

Respiratory

Check **respiratory rate** and patterns continuously.

- A. Goal SpO2 > 94% (*ideal-alarm if <94%*)
Note: One instance of hypoxia has significant negative impact on outcome. Continuously ensure adequate oxygenation.
- B. Goal **EtCO2 35-45mm Hg**. (*ideal-alarm when EtCO2 <35*)
- C. Ventilation strategy for the intubated patient aimed at minimizing mean airway pressure, maximizing oxygenation and maintaining PCo2 within normal limits

Cardiovascular

Maintain BP/CPP (*link to CPP formula: CPP=MAP-ICP, presume ICP 20 in TBI*)

- A. Age <1, MAP > 50 (*ideal-alarm if <50*)
- B. Age 1-8 yrs, MAP > 70 (*ideal-alarm if <70*)
- C. Age ≥8, MAP > 80 (*ideal-alarm if <80*)
- D. IF MAP < goal, **push NS 20 mL/kg. Repeat X 1 as needed for MAP < goal**
- E. Consider **dopamine** (5-10 mcg/kg/min), or **norepinephrine** (0.05-0.1 mcg/kg/min) if concern for spinal shock
Note: One instance of hypotension has significant negative impact on outcome. Treat hypotension aggressively **DO NOT** treat with anti-hypertensives without consulting with receiving MD
- F. Consider PRBC administration if Hgb < 8

Neurologic

1. IF **↓LOC, pupillary changes, ↓HR, ↑BP** (*link to age specific HR and BP table*)
 - A. Via ventilator or BVM: ↑RR to EtCO2 25-30mm Hg for ≤5 min. (*timer for 5 min "You have been hyperventilating for 5 min. Decrease RR back to baseline"*)
 - B. 3% NaCl (6 mL/kg) or Mannitol (0.5 gm/kg) (*link to Mannitol protocol*)
2. IF **seizure activity** present,
 - A. Midazolam 0.1 mg/kg or lorazepam 0.1 mg/kg
 - B. Fosphenytoin or phenytoin 20 mg/kg
3. If intubated, **maintain sedation and analgesia** and consider paralytic
 - A. Fentanyl 1 mcg/kg or morphine 0.1 mg/kg
 - B. Midazolam 0.1 mg/kg
 - C. **Avoid** propofol due to risk of hypotension
 - D. Vecuronium 0.1 mg/kg or rocuronium 1 mg/kg

Fluids and electrolytes

1. Check blood **glucose**
 - A. If >150 mg/dl do not give dextrose-containing fluids. Use NS as maintenance
 - B. If <80 mg/dl give D10W at 5 mL/kg slow push over 10 min, then use D5NS as maintenance
 - C. If glucose has been treated, repeat fingerstick glucose checks q 15 minutes throughout transport
2. Check **Na**
 - A. If Na < 135 AND 3% NaCl available, give 3% NaCl 6 mL/kg over 60 min. (*see 3% NaCl protocol*)

Maintenance

1. Position patient
 - A. **Elevate** patient's head **10-30°** if practical.
 - B. Maintain head in **midline**.

- C. Cervical collar
- 2. Maintain **temperature** 35-37°C. Do NOT warm aggressively
 - A. Acetaminophen 15 mg/kg ng or pr
 - B. Continuous temperature monitoring is indicated
 - C. **Avoid hyperthermia**
- 3. Protect affected body parts from injury.

**Table 2. Pediatric Glasgow Coma Scale
For Pre-verbal Children.**

Eye opening

Spontaneous	4
To speech	3
To pain	2
No response	1

Verbal response

Coos, babbles	5
Irritable cry	4
Cries to pain	3
Moans to pain	2
No response	1

Motor response

Follows commands	6
Localizes pain	5
Withdraws to pain	4
Decorticate flexion	3
Decerebrate extension	2
No response	1

Appendix 3:

CHRCO DKA Treatment Algorithm

“First hour” actually starts when the patient receives treatment (fluid or insulin therapy) at the sending facility.

DKA algorithm timer should alert transport clinician q 50 minutes as management decisions are suggested hourly.

- 1) On arrival of transport team: Evaluate if “first hour” management has been completely implemented. If not, address deficiencies.
- 2) First Hour –
 - a. Establish IV (2 if possible).
 - b. Labs –
 - i. Check results of venous or capillary blood gas with electrolytes, blood glucose, bun, creat, cbc, phosphorus.
 - ii. If above labs NOT sent by time transport team arrives, send point of care blood gas with electrolytes and glucose alone. (Will send remainder on arrival to CHRCO.)
 - c. Fluid bolus with isotonic fluids – NS, LR, Plasmalyte. 20ml/kg ok. Consider repeat 20 mL/kg ONLY if hemodynamics are unstable.
 - i. Most patients need < 40 mL/kg fluid prior to arrival to PICU.
 - ii. Goal of fluid resuscitation is to assure perfusion and restore blood pressure NOT to normalize HR and mentation.
 - iii. NO Bolus insulin.
 - iv. NO sodium bicarbonate UNLESS patient hypotensive or in cardiopulmonary arrest.
- 3) Second hour –
 - a. Recheck blood glucose (hourly)
 - b. Assess labs sent in first hour.
 - c. Start insulin infusion – NOT bolus insulin
 - i. Regular Humulin Insulin 250 units/250mL NS at 0.1 units/kg/hour, or 0.05 units/kg/hr in (toddlers/infants) to 0.1 units/kg/hour.
 - d. IV fluids
 - i. If $K > 5.0$ and/or if NO urine output
 1. NS at 1.5 x maintenance
 - ii. If $K < 5.0$ AND urine output documented
 1. NS + 20meq/l KCL + 20 meq/Kphos
 - a. If no Kphos available, then NS + 40 meq KCL/L
 - b. If NS + 40 meq KCL/L not available, then NS + 20meq KCL/L
 - iii. When glucose ≤ 250
 1. If $K > 5$ and/or if NO urine output
 - a. D10 NS + 20meq KCL/L + 20 meq Kphos/L
 2. If $K < 5$ AND urine output documented
 - a. D10 NS+ 20meq KCL/L + 20 meq Kphos/L
 - b. If no Kphos available, then D10 NS + 40 meq KCL/L
 - c. If D10 NS + 40 meq KCL/L not available, then D5 NS + 20meq KCL/L and recheck glucose in 30 minutes!
- 4) Thereafter
 - a. Check mentation continuously
 - i. If altered mentation,

1. PUSH
 - a. 6 mL/kg of 3% saline (hypertonic saline) = 3 meq/kg (preferred)
 - b. 0.5 gm/kg mannitol (may be more widely available)
2. Consider CT scan
3. Consider controlling airway (*link to respiratory failure algorithm WITH increased intracranial pressure precautions*)
- b. Check glucose hourly
 - i. If glucose dropping by > 100 mg/dL consider INCREASING fluids to 2X maintenance and/or INCREASING dextrose in IVF, or TEMPORARILY decreasing insulin infusion (to 0.05 Units/kg/hour)
- c. Check VBG with lytes q 2 hourly
- d. Note: Ice chips generally ok to give patient for dry mouth but otherwise patient remains STRICTLY NPO.